

Equivalent of Form PTO/SB/08A (09-06)

Substitute for form 1449/PTO Fourth Supplemental INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/555,343
				Filing Date	(§ 371 Date) November 1, 2005
				First Named Inventor	KATO <i>et al.</i>
				Art Unit	1614
				Examiner Name	Craig D. Ricci
				Attorney Docket Number	1089.0590000/MAC
Sheet	1	of	1		

[illegible][illegible]

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Examiner Signature	/Craig Ricci/	Date Considered	03/25/2010
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.R./

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	NPL21	Lückel, B., <i>et al.</i> , "A Strategy for Optimizing the Lyophilization of Biotechnological Products," Pharm. Sc. 3(1): 3-8, The Royal Pharmaceutical Society of Great Britain, London, England, (January, 1997)	
	NPL22	Roberts, C.,J. <i>et al.</i> , "Engineering Pharmaceutical Stability with Amorphous Solids," AIChE Journal 48(6): 1140-1144, The American Institute of Chemical Engineers, New York, (June, 2002)	
	NPL23	Telang, C. <i>et al.</i> , Effective Inhibition of Mannitol Crystallization in Frozen Solutions by Sodium Chloride," Pharm. Res. 20(4): 660-667, Kluwer Academic/Plenum publishers, Dordrecht, The Netherlands, (April, 2003)	

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